

Substitute for form 1449B/PTO

**SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT
IN AN APPLICATION**

LISTING OF REFERENCES

May 27, 2008

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
3506.1023-000

APPLICATION NO.
10/617,847

FIRST NAMED INVENTOR
Hazel Judith Bardsley

FILING DATE
July 10, 2003

EXAMINER
Layla Soroush

CONFIRMATION NO.
7988

GROUP
1617

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	U2	4,845,092	07-04-1989	Sanger <i>et al.</i>
	U3	4,939,136	07-03-1990	Haeck <i>et al.</i>
	U4	5,225,407	07-06-1993	Oakley <i>et al.</i>
	U5	5,352,685	10-04-1994	Maruyama <i>et al.</i>
	U6	5,434,174	07-18-1995	Gidda <i>et al.</i>
	U7	5,438,068	08-01-1995	Eeckhout <i>et al.</i>
	U8	5,470,868	11-28-1995	Young
	U9	5,530,008	06-25-1996	Azcona <i>et al.</i>
	U10	5,576,317	11-19-1996	Gonsalves
	U11	5,663,343	09-02-1997	van der Meij <i>et al.</i>
	U12	5,945,415	08-31-1999	Kato <i>et al.</i>
	U13	5,962,494	10-05-1999	Young
	U14	5,977,127	11-02-1999	Bonnacker <i>et al.</i>
	U15	5,977,175	11-02-1999	Lin
	U16	5,985,866	11-16-1999	Müller <i>et al.</i>
	U17	5,990,159	11-23-1999	Meulemans <i>et al.</i>
	U18	6,008,227	12-28-1999	Davies <i>et al.</i>
	U19	6,054,461	04-25-2000	Fairbanks <i>et al.</i>
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	U21	6,156,771	12-05-2000	Rubin <i>et al.</i>

EXAMINER

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	U22	6,194,382	02-27-2001	Crain, <i>et al.</i>
	U23	6,211,171 B1	04-03-2001	Sawynok <i>et al.</i>
	U24	6,235,745 B1	05-22-2001	Megens
	U25	6,284,770 B1	09-04-2001	Mangel <i>et al.</i>
	U26	2001/0020025 A1	09-06-2001	Megens
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	U28	2001/0044450 A1	11-22-2001	Mangel <i>et al.</i>
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	U39	6,440,453 B1	08-27-2002	Fischer <i>et al.</i>
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	U42	6,465,458 B1	10-15-2002	Wong <i>et al.</i>
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	U49	6,593,336 B2	07-15-2003	Mangel <i>et al.</i>
	U50	2003/0158221 A1	08-21-2003	Zhang <i>et al.</i>
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	U52	2006/0217391 A1	09-28-2006	Landau
	U53	2004/0147509 A1	07-29-2004	Landau
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	U62	2005/0192270 A1	09-01-2005	Landau
	U63	2005/0222162 A1	10-06-2005	Cavalla <i>et al.</i>
	U64	2005/0239792	10-27-2005	Cavalla <i>et al.</i>
	U65	2006/0167005 A1	07-27-2006	Cavalla <i>et al.</i>
	U66	7,094,786	08-22-2006	Landau

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	F2	EP 0 297 651 B1	11-03-1993	Duphar International Research B.V		
	F3	WO 94/01095	01-20-1994	Smith-Kline Beecham PLC		
	F4	WO 98/50037	11-12-1998	Mitsubishi Chemical Corporation		X
	F5	WO 00/48581 A3	08-24-2000	Novartis AG		
	F6	WO 00/48597	08-24-2000	Novartis AG		
	F7	WO 00/51583	09-08-2000	Sepracor, Inc.		
	F8	WO 00/51584	09-08-2000	Sepracor, Inc.		
	F9	WO 01/26623 A3/A2	04-19-2001	Laxdale Limited		
	F10	WO 02/07713 A2	01-31-2002	Solvay Pharmaceuticals GMBH		X
	F11	DE 100 63 223 A1	6-20-2002	Merck Patent GMBH		X
	F12	CA 2431074	6-27-2002	Merck Patent GMBH		
	F13	EP 1 230 921 A1	08-14-2002	Pfizer Products, Inc.		
	F14	WO 02/083926 A3/A2	10-24-2002	Cedars-Sinai Medical Center		
	F15	WO 02/094249 A1	11-28-2002	Arachnova Therapeutics Ltd.		
	F16	WO 03/061657 A1	07-31-2003	Aryx Therapeutics		
	F17	WO 03/063873 A1	08-07-2003	Arachnova Therapeutics, Ltd.		
	F18	WO 03/077897 A1	09-25-2003	Cypress Bioscience, Inc.		
	F19	WO 2004/004734 A1	01-15-2004	Arachnova Therapeutics Ltd.		
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	F21	WO 2004/058353 A3/A2	07-15-2004	Amedis Pharmaceuticals, LTD.		
	F22	WO 2004/062623 A2	07-29-2004	Dynogen Pharmaceuticals, Inc.		
	F23	WO 2004/062624 A3/A2	07-29-2004	Dynogen Pharmaceuticals, Inc.		
	F24	EP 0150469	06-15-1988	Mitsubishi Chemical Industries Limited		

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C1	"How to Avoid a Health Insurance Claim Denial- and What to do When You Can't," [Retrieved on 03-15-2005]. Retrieved from the Internet <URL:http://info.insure.com/health/claimdenial.html>, pp 1-4.	
C2	"Irritable Bowel Syndrome at a Glance - Nosology, Epidemiology, and Pathophysiology (Monograph I), December 2002 [Retrieved on 2002-12-12]. Retrieved from the Internet <URL:http://fdhn.org/html/education/gi/ibs_nosology.htm>, pp. 1-2.	
C3	"Dynogen Pharmaceuticals, Inc. Enters Into Agreement With Mitsubishi Pharma For Irritable Bowel Syndrome Compound," Dynogen Pharmaceuticals, Inc. Press Release, pp. 1-2 [online], (December 22, 2003). Retrieved from the Internet <URL: www.dynogen.com>.	
C4	Angel, I., <i>et al.</i> "Litoxetine: A Selective 5-HT Uptake Inhibitor with Concomitant 5-HT ₃ Receptor Antagonist and Antiemetic Properties," <i>Eur. J. Pharmacol.</i> , 232(2/3):139-145 (1993).	
C5	Béique, J.C., <i>et al.</i> , "Affinities of Venlafaxine and Various Reuptake Inhibitors for the Serotonin and Norepinephrine Transporters," <i>Eur. J. Pharmacol.</i> , 349(1):129-132 (1998).	
C6	Burns, M.J., "The Pharmacology and Toxicology of Reboxetine," <i>Int. J. Med. Toxicol.</i> 3(4):26 1-7 (2000).	
C7	Bymaster, F.P., <i>et al.</i> "Comparative Affinity of Duloxetine and Venlafaxine for Serotonin and Norepinephrine Transporters <i>in vitro</i> and <i>in vivo</i> , Human Serotonin Receptor Subtypes, and Other Neuronal Receptors," <i>Neuropsychopharmacology</i> , 25(6):871-880 (2001).	
C8	Camilleri, M., "Serotonergic Drugs: Emerging Therapies for Irritable Bowel Syndrome," <i>In Irritable Bowel Syndrome a Clinician's Guide</i> , M. Camilleri and R. C. Spiller, <i>eds.</i> , Chapt. 19; pp 1-10 (2002).	
C9	Camilleri, M., "Serotonergic Modulation of Visceral Sensation: Lower Gut," <i>Gut</i> 51(Supp. 1):i81-i86 (2002).	
C10	Center for Drug Evaluation and Research Application Number: 020623; Pharmacology Reviews; July 5, 1996, pp. 1-40.	
C11	Crowell, M. D., "The Role of Serotonin in the Pathophysiology of Irritable Bowel Syndrome," <i>Am. J. Man. Care</i> , 7(8 Supp.): S252-S260 (2001).	
C12	Database CIN 2004-01-05, "Life Sciences in Brief," [online], January 5, 2004 (retrieved online January 31, 2006). Retrieved from: STN Database, Accession No. 33(3):1518T.	

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C13	Database IMSDRUGNEWS, R&D Focus Drug News, "DDP 225 Dynogen, Mitsubishi Pharma Licensing Agreement," [online], January 12, 2004. Retrieved from: STN Database, Accession No. 2004:188.
C14	Depoortere, I., <i>et al.</i> , "Dose-Dependent Effects of Recombinant Human Interleukin-11 on Contractile Properties in Rabbit 2,4,6-Trinitrobenzene Sulfonic Acid Colitis," <i>J. Pharmacol. Exp. Ther.</i> , 294(3): 983-990 (2000).
C15	Drossman, D.A., <i>et al.</i> , "Irritable Bowel Syndrome: A Technical Review for Practice Guideline Development," <i>Gastroenterology</i> , 112: 2120-2137 (1997).
C16	Eguchi, J., <i>et al.</i> , "Pharmacological Profile of the Novel Antidepressant 4-(2-Fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno-[2,3-d]pyrimidine Monohydrate Hydrochloride," <i>Arzneim.-Forsch./Drug Res.</i> , 47(12): 1337-1347 (1997).
C17	Eguchi, J., <i>et al.</i> , "The Anxiolytic-Like Effect of MCI-225, A Selective NA Reuptake Inhibitor with 5-HT ₃ Receptor Antagonism," <i>Pharm. Biochem. and Behavior</i> , 68:677-683 (2001).
C18	Fairweather, D.B., <i>et al.</i> , "The Psychomotor and Cognitive Effects of Litoxetine in Young and Middle Aged Volunteers," <i>Br. J. Clin. Pharmacol.</i> , 40(2):119-125 (1995).
C19	GB 0216027.3, filed July 10, 2002, entitled "New Therapeutic Use," priority document for WO 2004/004734 A1.
C20	GB 0304648.9, filed 02-28-2003, entitled "New Therapeutic Use of 4-(2-Fluorophenyl)-6-Methyl-2-(1-Piperazinyl) Thieno[2,3-D] Pyrimidine," priority document for WO 2004/004734 A1.
C21	Gebhart, G.F., "Pathobiology of Visceral Pain: Molecular Mechanisms and Therapeutic Implications IV. Visceral Afferent Contributions to the Pathobiology of Visceral Pain," <i>Am. J. Physiol. Gastrointest. Liver Physiol.</i> 278:G834-G838 (2000).
C22	Goldberg, P.A., <i>et al.</i> , "Modification of Visceral Sensitivity and Pain in Irritable Bowel Syndrome by 5-HT ₃ Antagonism (Ondansetron)," <i>Digestion</i> , 57(6):478-483 (1996).
C23	Greenbaum, D.S., <i>et al.</i> , "Effects of Desipramine on Irritable Bowel Syndrome Compared with Atropine and Placebo," <i>Digestive Diseases and Sciences</i> , 32(3): 257-266 (1987).
C24	Ishigooka, Jr., <i>et al.</i> , "Serotonin-Noradrenaline Reuptake Inhibitors(SNRIs)," <i>Nippon Rinsho</i> , 59, pp. 1523-9, (2001) - Abstract Only.
C25	Ito, C., <i>et al.</i> , "Effect of GK-128 [2-[(2-Methylimidazol-1-yl)methyl]- benzo[f]thiochromen-1-one Monohydrochloride Hemihydrate], a Selective 5-Hydroxytryptamine ₃ Receptor Antagonist, on Colonic Function in Rats," <i>J. Pharmacol. Exp. Ther.</i> , 280(1): 67-72 (1997).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C26	Jin, J.G., <i>et al.</i> , "Propulsion in Guinea Pig Colon Induced by 5-Hydroxytryptamine (HT) via 5-HT ₄ and 5-HT ₃ Receptors," <i>J. Pharmacol. Exp. Ther.</i> , 288(1): 93-97 (1999).	
C27	Kozlowski, C.M., <i>et al.</i> , "The 5-HT ₃ Receptor Antagonist Alosetron Inhibits the Colorectal Distention Induced Depressor Response and Spinal <i>c-fos</i> Expression in the Anaesthetised Rat," <i>Gut</i> , 46: 474-480 (2000).	
C28	LOTRONEX - Tablets, Product Information, GlaxoSmithKline, Research Triangle Park, NC, pp. 1-13 (2002).	
C29	Mertz, H.R., "Irritable Bowel Syndrome," <i>N. Engl. J. Med.</i> 349(22):2136-2146 (2003).	
C30	Million, M., <i>et al.</i> , "Susceptibility of Lewis and Fischer Rats to Stress-induced Worsening of TNB-colitis: Protective Role of Brain CRF," <i>Amer. Phys. Soc.</i> , 276 (4 Pt 1): G1027-G1036 (1999).	
C31	Morteau, O., <i>et al.</i> , "Influence of 5-HT ₃ Receptor Antagonists in Visceromotor and Nociceptive Responses to Rectal Distension Before and During Experimental Colitis In Rats," <i>Fundam. Clin. Pharmacol.</i> , 8(6):553-562 (1994).	
C32	Owens, M. J., <i>et al.</i> , "Neurotransmitter Receptor and Transporter Binding Profile of Antidepressants and their Metabolites," <i>J. Pharmacol. Exp. Ther.</i> , 283(3): 1305-1322 (1997).	
C33	Sach, J.A., <i>et al.</i> , "Irritable Bowel Syndrome," <i>Curr. Treat. Options. Gastroenterol.</i> , 5(4): 267-278 (2002).	
C34	Schmulson, M.J., "Brain-Gut Interaction in Irritable Bowel Syndrome: New Findings of a Multicomponent Disease Model," <i>IMAJ</i> , 3:104-110 (2001).	
C35	Sheikh, M. Y. and Wright, R.A., "Irritable Bowel Syndrome: Current Concepts and Future Prospects," <i>Hospital Physician</i> , pp. 31-38 (1999).	
C36	Spiller, R., "Pharmacotherapy: Non-Serotonergic Mechanisms," <i>Gut</i> , 51, Suppl, i87-i90 (2002).	
C37	Steadman, C.J., <i>et al.</i> , "Selective 5-Hydroxytryptamine Type 3 Receptor Antagonism With Ondansetron as Treatment for Diarrhea-Predominant Irritable Bowel Syndrome: A Pilot Study," <i>Mayo Clinic Proc.</i> , 67(8): 732-738 (1992).	
C38	Thompson, W.G., <i>et al.</i> , "Functional Bowel Disorders and Functional Abdominal Pain," <i>Gut</i> 45(Supp II):II43-II47 (1999).	
C39	U.S. Provisional Application No. 60/364,531, filed 03-15-2002, entitled "Methods of Treating Visceral Pain Syndromes," by Rao <i>et al.</i> , priority document for WO 03/077897 A1 and U.S. 2003/0203055 A1.	

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C40	Venkova, K., <i>et al.</i> , "Peripheral Activity of a New NK ₁ Receptor Antagonist TAK-637 in the Gastrointestinal Tract," <i>J. Pharmacol. Exp. Ther.</i> , 300(3): 1046-1052 (2002).	
C41	Wong, E.H.F., <i>et al.</i> , "Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor," <i>Biol. Psychiatry</i> . 47(9): 818-829 (2000).	
C42	Wood, J.D., <i>et al.</i> "Fundamentals of Neurogastroenterology," <i>Gut</i> 45(Supp. II):II6-II16 (1999).	
C43	Yuan, S.Y., <i>et al.</i> , "Investigation of the Role of 5-HT ₃ and 5-HT ₄ Receptors in Ascending and Descending Reflexes to the Circular Muscle of Guinea-pig Small Intestine," <i>Br. J. Pharmacol.</i> , 112(4): 1095-1100 (1994).	

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